REMARKS

Applicant respectfully submits that the subject matter of the claims in Group I and the claims in Group II are not "distinct" and that the Office Action fails to meet the requirements for adequately demonstrating that the inventions are "distinct." As stated in MPEP § 806.05(h):

> Product and Process of Using:
>
> A product and a process of using the product can be shown to be distinct inventions if either or both of the following can be shown: (A) the process of using as claimed can be practiced with another materially different product; or (B) the product as claimed can be used in a materially different process.
>
> The burden is on the examiner to provide an example, but the example need not be documented.

(Emphasis added.)

The Office Action purports to comply with these requirements by asserting:

> In the instant case the product can be used in a materially different process of using such as in a pharmaceutical fermentor to introduce growth media into a bioreactor.

(Office Action, p. 2; emphasis added)

The restriction requirement is improper because it fails to comply with fundamental requirements of proper restriction practice under U.S. Patent Office standards. A fundamental tenet of that practice is the requirement that the restriction requirement focus on the claimed subject matter. Indeed at the very outset of the section on restrictions, the MPEP states:

> 806.01 Compare Claimed Subject Matter [R-3] - 800 Restriction in Applications Filed Under 35 U.S.C. 111; Double Patenting

> In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence.

(MPEP § 806.01; emphasis added)

The Office Action restriction requirement is fatally defective because it fails to consider the claimed subject matter in reaching the conclusion that the subject matter of the Group I claims is distinct from the subject matter of the Group II claims.

Claim 1, the sole independent claim in Group I, states:

> 1. A system for accurately delivering sterile fluids for use in a cosmetic surgery procedure comprising:
>
> a strain gauge sensor;
>
> a container of sterile fluid connected to the strain-gauge sensor so that the strain-gauge sensor will generate an electrical output proportional to the weight of the fluid and container from time-to-time;
>
> a pump for pumping fluid from the container and having adjustable speed control for delivery of fluids within the range of 30 ml/min to 1000 ml/min;
>
> a sterile tubing set connected to the fluid source and the pump for delivery of the sterile fluid during the surgical procedure;
>
> a processor for processing the electrical output from the strain gauge from time-to-time to determine the amount of fluid delivered to the surgical procedure, and
>
> a display for displaying the amount of fluid delivered during the surgical procedure.

(Claim 1; emphasis added.)

Similarly, Claim 10, the sole independent claim in Group II, states:

> 10. A method for accurately delivering sterile fluids for use in a cosmetic surgery procedure comprising:

supporting a container of sterile fluid connected to the strain-gauge sensor so that the strain-gauge sensor provides an electronic signal indicative of the weight of the container and sterile fluid from time-to-time;

connecting one end of a sterile tubing set to the fluid container and passing the tubing set through a pump so that the pump can remove sterile fluid from the container within the range of 30 ml/min to 1000 ml/min;

making the other end of the sterile tubing set available for delivery of the sterile fluid by the pump to the cosmetic surgery procedure,

activating the pump to pump fluid from the fluid source to the patient or the implantable device at a desired flow rate;

processing the electronic signal from the strain gauge to display the amount of sterile fluid removed from the container from time-to-time; and

monitoring the amount of sterile fluid pumped to the cosmetic surgery procedure;

releasing the pump activation when the desired amount of sterile fluid has been provided for the cosmetic surgery procedure.

(Claim 10; emphasis added.)

Even a cursory review of these claims, demonstrates that the "product as claimed" cannot be used in a "materially different process . . . such as in a pharmaceutical fermentor to introduce growth media into a bioreactor." The process "as claimed" does not include such a use. The only way that such a result could be achieved is if the numerous references to "sterile fluid" and "surgical procedure" were read out of the claims.[1] This is not appropriate under MPEP §§ 806.01 and 806.05(h).

Thus, the Office Action fails to meet the requirement to cite an example showing that the subject matter of the two groups of claims are distinct. (MPEP § 806.05(h).) The requirement for an election between the two groups is improper.

[1] While the object being acted on (i.e., sterile fluid) and the use are set forth in the preamble, those same limitations appear in the body of the claim. It would be improper to ignore them.

In sum, applicant traverses the requirement for a restriction because it appears to have employed an inappropriate standard and fails to document the basis for asserting distinctness as required by the MPEP. A proper example has not been provided showing that the system "as claimed" in Group I can be employed in a process other than that claimed in Group II.

While the Office Action alludes to separate classification of the subject matter, the subject matter of Group I and of Group II falls within the same class. More importantly, a proper search of either the Group I or Group II claims would include a search of both the subclasses referenced in the Office Action. (Office Action, p. 2.) Both the Group I and Group II claims reference a "pump" (Class 604, Subclass 151 – "material impelled by pump") and reference a "sensor" that is involved in controlling the pump (Class 604, Subclass 67 – "sensor controls pump, motor, or pressure driven means"). Thus, the Office Action is not correct in asserting that the subject matter of the Group I and Group II claims "have acquired a separate status in the art as shown by their different classification . . . ." Finally, even if the subject matter of the two groups of claims were separately classified, separate classification by itself is not a proper basis for a restriction requirement.

Accordingly, applicant respectfully submits that the restriction requirement is improper and should be withdrawn and that all of the claims pending in this application should be examined together. When proper focus is placed on the claimed subject matter as required by MPEP §§ 806.01 and 806.05(h), it is apparent that the Group I and Group II claims are neither distinct nor separately classified.

Submitted concurrently with this Response is a petition requesting a five-months' extension of time and the requisite fee of $225.00. Applicant respectfully submits that no other fee is required in connection with this Response. In the event that the fee has been improperly calculated, you are hereby authorized to charge any additional fees or to credit any overpayment to Deposit Account No. 13-2725 with respect to Attorney Docket No. 40206.19-US-U1.

Respectfully submitted this 21st day of February 2006.

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